

**Instruction Guide for Cleaning, Testing, and Packaging
Kendall SCD™ 700 Sequential Compression System
Controller and Tubing Set**

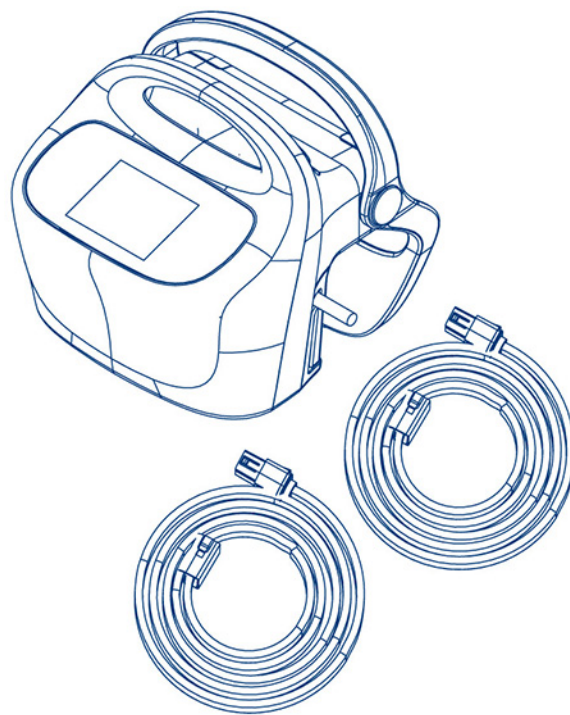


TABLE OF CONTENTS

Section 1 – Instructions for UNUSED Units	2
Confirm Kit Materials	2
Apply DME Label to Kendall SCD™ 700 Controller	2
Packaging Instructions	3
Section 2 – Instructions for Customer Returned Units	5
Reference Documents	5
Equipment List	5
Preparation	5
Tubing Set:	7
Visual Inspection	7
Cleaning	7
Leak Test	7
Kendall SCD™ 700 Controller:	9
Visual Inspection	9
Cleaning	10
General Function Test	10
Re-Packaging Procedure:	11
Kit Materials	11
Packaging Instructions	11
Attachment A – Instructions for Returning Damaged Controllers	13

Section 1 – Instructions for UNUSED Units

CONFIRM KIT MATERIALS

- Verify that all the following materials are available:

Part Description	Quantity	Part #	Vendor	Contact Info
New Kendall SCD™ 700 compression system	1	H29525	Covidien	1-800-962-9888 www.covidien.com
Return Label	1	N/A	N/A	N/A
Twist Ties, Blue Plastic	1	F150023	Covidien	1-800-962-9888 www.covidien.com
Kendall SCD™ 700 controller QuickStart Guide	1	1066981	Covidien	1-800-962-9888 www.covidien.com
Kendall SCD™ 700 controller Printed IFU	1	1066980	Covidien	1-800-962-9888 www.covidien.com

APPLY DME LABEL TO KENDALL SCD™ 700 CONTROLLER

- Remove home controller from the packaging and take out of the polybag and AIR-PAQ™* inflatable packaging.
- Create a label that provides the DME supplier contact information. At a minimum, the information should contain the following:
 - Company name
 - Company address
 - Company telephone number
- Apply DME supplier contact information label on the front of the controller, approximately centered in the area indicated by the box in the sketch below (on the front of the controller, below the control panel):



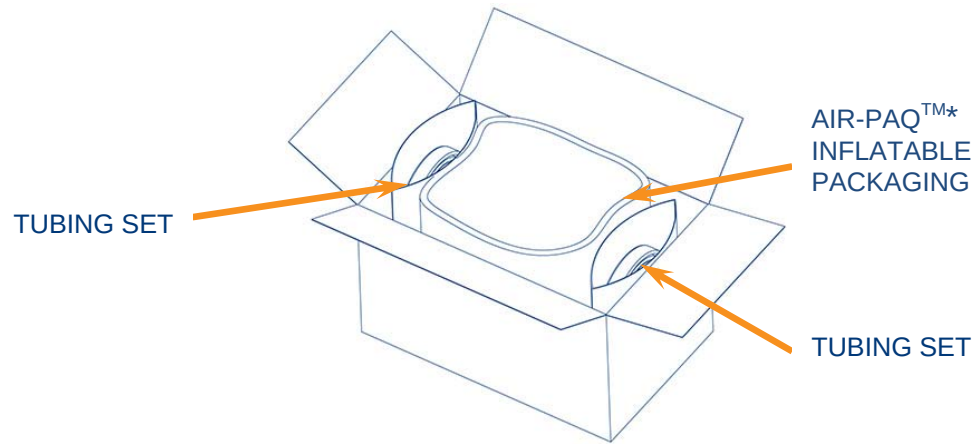
PLACE LABEL WITHIN THE BOXED AREA

- Place home controller back into the polybag and AIR-PAQ™* inflatable packaging.
- Place the printed IFU into the shipping box.

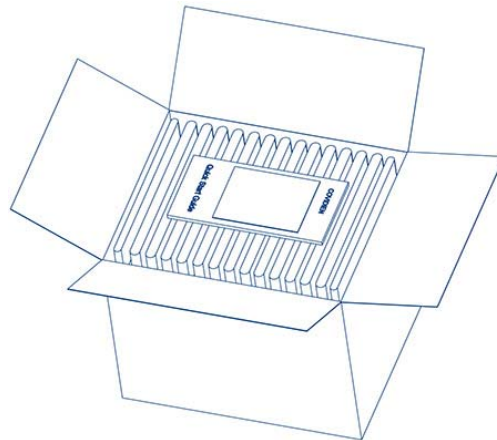
Section 1 – Instructions for UNUSED Units (continued)

PACKAGING INSTRUCTIONS

- Re-package the home controller in the polybag and AIR-PAQ™* inflatable packaging. Place the tubing sets into the original package the way it was received (see picture below).



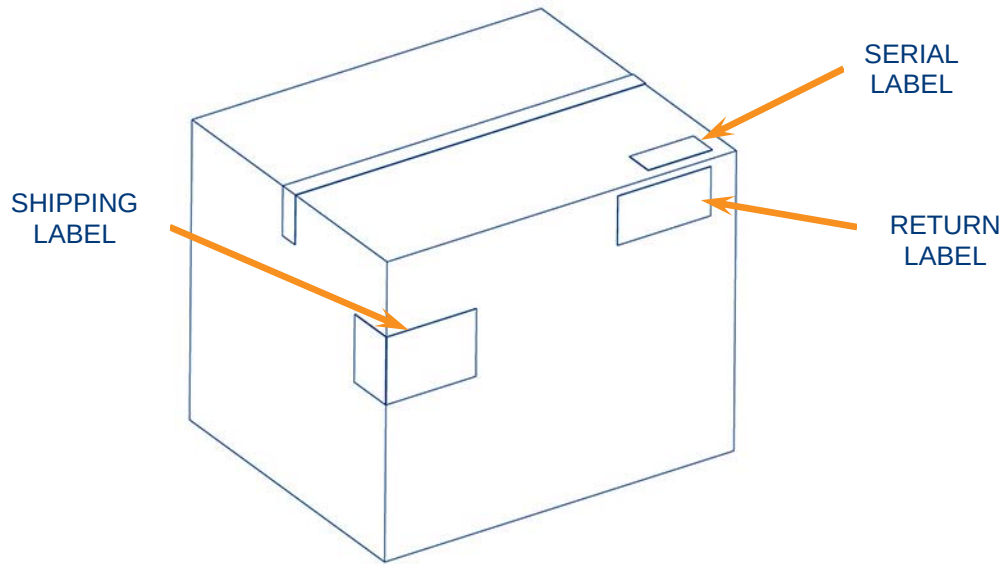
- Place the QuickStart Guide on top of the AIR-PAQ™* inflatable packaging as shown below:



Section 1 – Instructions for UNUSED Units (continued)

PACKAGING INSTRUCTIONS (continued)

- Seal the top of the box and confirm all labels are visible on the outside of the shipping box as shown below:
 - o Serial label on the top of the shipping box;
 - o Shipping label on the front wrapping on the left side;
 - o Return label to the right of the shipper label and beneath the serial label.



Section 2 – Instructions for Customer Returned Units

REFERENCE DOCUMENTS

- Kendall SCD™ 700 system Operation and Service Manual

EQUIPMENT LIST

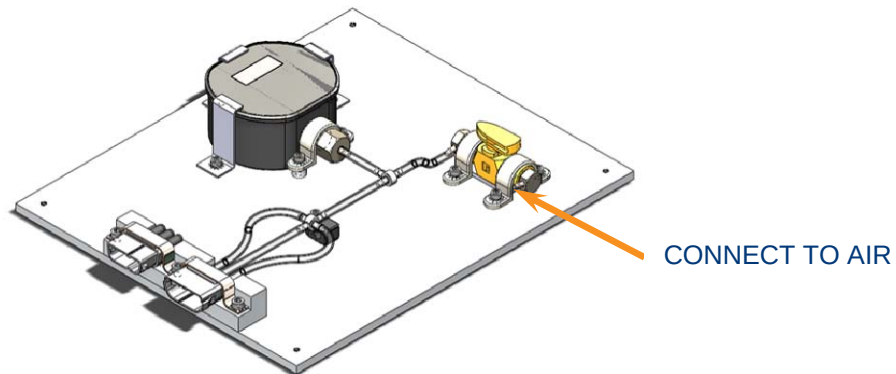
- Regulated air source (i.e. compressor or factory air)
- Tubing set Leak Test Fixture (provided by Covidien)
- Known good tubing set

PREPARATION

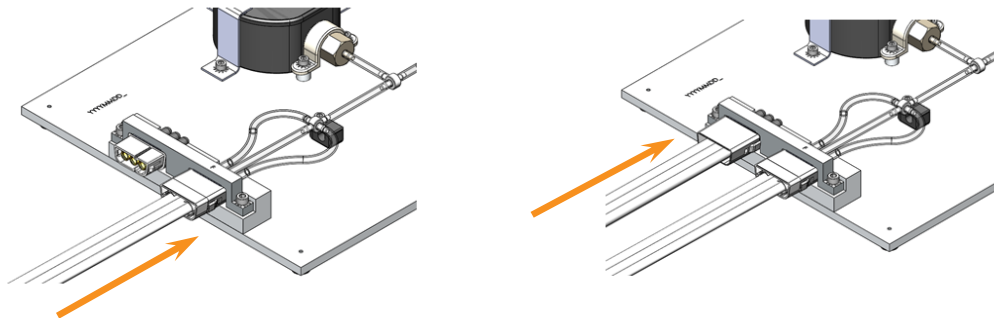
- TUBING SET LEAK TEST FIXTURE SETUP:

NOTE: This is to be performed upon receipt of the fixture, to confirm acceptable fixture functionality.

- o Confirm the tubing set Leak Test Fixture's certification from the fixture manufacturer.
- o Confirm pressure gauge is calibrated. If not, send out for re-calibration.
- o Conduct the leak test with the known good tubing set as follows:
 - Ensure that the Leak Test Fixture (see sketch below) is connected to a regulated air source. The input air should be at pressure between 3 psi and 4 psi.



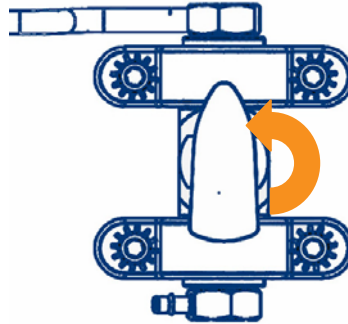
- Connect the tubing set to the connectors on the test fixture. See pictures below.



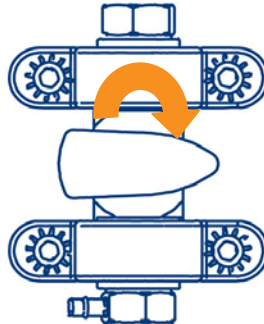
Section 2 – Instructions for Customer Returned Units (continued)

PREPARATION (continued)

- TUBING SET LEAK TEST (continued):
 - Turn ball valve to open position, so that the knob position is in-line with valve body (see picture below).



- Adjust the input air pressure so that a pressure of between 125mmHg (2.4 psi) and 135mmHg (2.6 psi) is indicated on the fixture's pressure gauge, and allow to hold for approximately 2 seconds.
- Close ball valve, so that the knob position is perpendicular to valve body (see picture below). Activate the stopwatch.



- Wait 15 seconds and observe the pressure gauge. Because the test was conducted with known good tubing set, the pressure should not fall below 89mmHg (1.72 psi). If pressure falls below 89mmHg, contact your sales rep for replacement tubing set Leak Test Fixture.

Section 2 – Instructions for Customer Returned Units (continued)

TUBING SET

VISUAL INSPECTION

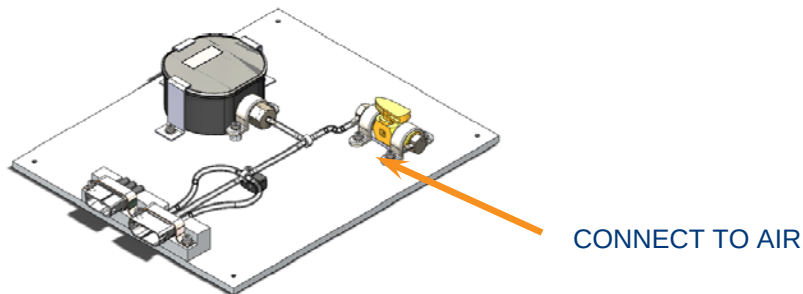
- Inspect the tubing sets for missing, broken or cracked components. If any components are missing, broken or cracked, discard the tubing set.
- Inspect the tubing set for condensation in the tubing. If condensation is present in the tubing, discard the tubing set.
- Inspect the printing on the tubing set connectors. If any connectors contain incomplete characters, discard the tubing set.

CLEANING

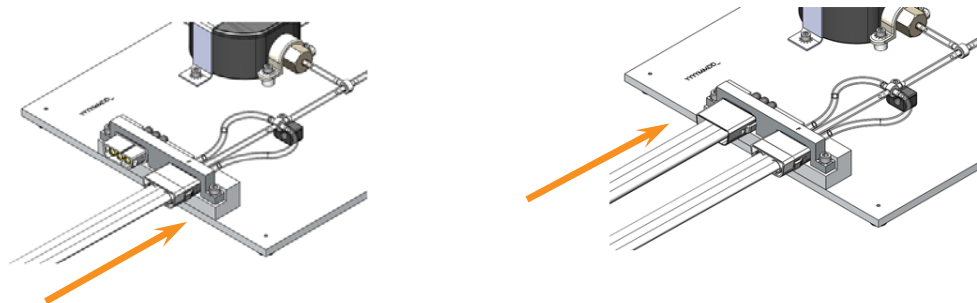
- Clean the customer returned tube set as per the Kendall SCD™ 700 system Operation and Service Manual.
- All visible extraneous markings or materials should be removed by the cleaning step. If extraneous markings or materials are not removed, discard the tubing set.

LEAK TEST

- Inspect the Leak Test Fixture to ensure that it is in working order and that the pressure gauge has a valid calibration date.
- Ensure that the Leak Test Fixture is connected to a regulated air source. The input air should be at pressure between 3 psi and 4 psi. See sketch below.



- Connect the Tubing Set to the connectors on the test fixture. See pictures below.

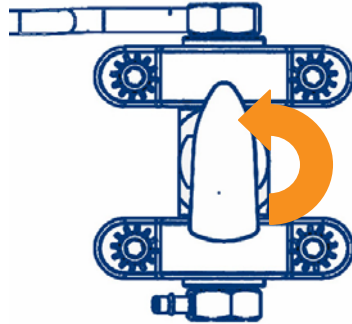


Section 2 – Instructions for Customer Returned Units (continued)

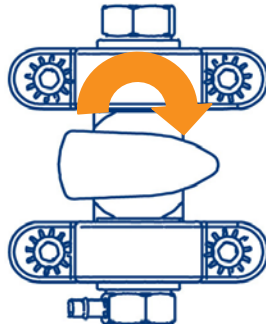
TUBING SET (continued)

LEAK TEST (continued)

- Turn ball valve to open position, so that the knob position is in-line with valve body (see picture below).



- Adjust the input air pressure so that a pressure of between 125mmHg (2.4 psi) and 135mmHg (2.6 psi) is indicated on the fixture's pressure gauge, and allow to hold for approximately 2 seconds.
- Close ball valve, so that the knob position is perpendicular to valve body (see picture below). Activate the stopwatch.



- Wait 15 seconds and observe pressure gauge. Pressure should not fall below 89mmHg (1.72 psi). If pressure falls below 89mmHg, the tubing set has a leak. Discard the tubing set.

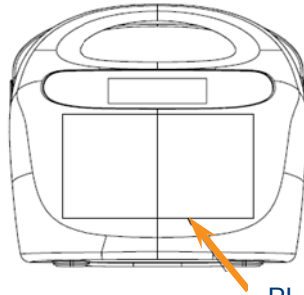
NOTE: If tubing set inspection and cleaning is not completed as per the steps above, discard the tubing sets and provide new tubing sets in the package.

Section 2 – Instructions for Customer Returned Units (continued)

KENDALL SCD™ 700 SYSTEM CONTROLLER

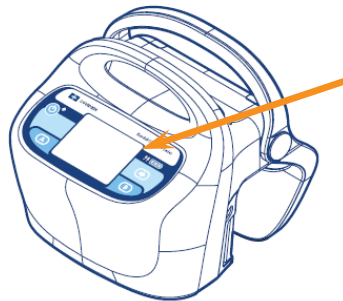
VISUAL INSPECTION

- Inspect the DME supplier contact information label. If the DME supplier contact information label is torn, ripped or illegible, replace with a new label (see sketch below):



PLACE LABEL WITHIN THE BOXED AREA

- Inspect the power cord for damage. If power cord is frayed or damaged, send the controller to the Covidien service center for repair (Reference Attachment A).
- Inspect the controller for marks, scuffs and scratches especially on the control panel (see below).



CONTROL PANEL

- Minor surface scratches or scuffs are acceptable. If any marks are present that obscure or interfere with the display of the icons or the clear membrane on the control panel, send the controller to the Covidien service center for repair (Attachment A).
- Inspect the controller for missing, broken or cracked components. If any components are missing, broken or cracked, send the controller to the Covidien service center for repair (Attachment A).
- Inspect the controller for the presence of the serial label on the bottom of the device. If the serial label is not present, or if it is illegible or damaged, send the controller to the Covidien service center for repair (Attachment A).

Section 2 – Instructions for Customer Returned Units (continued)

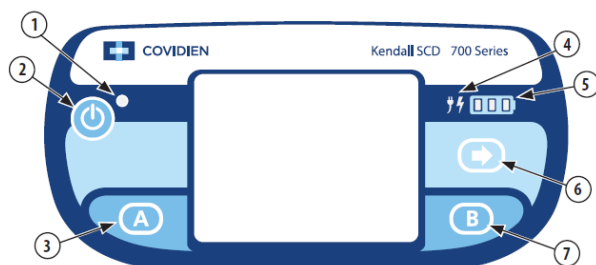
KENDALL SCD™ 700 CONTROLLER (continued)

CLEANING

- Unplug the controller from Mains voltage before cleaning.
- Clean the customer returned Kendall SCD™ 700 controller as per the Kendall SCD™ 700 system Operation and Service Manual.

GENERAL FUNCTION TEST

- With no tubing set connected to the SCD™ 700 controller, connect the controller to AC power. Verify that the power source light (power on indicator) turns on. Note: Controller must be connected to AC power to enter test mode.
- See front panel display below:



Item	Explanation	Item	Explanation
1	Power On Indicator	5	Battery Status Indicators 1-3
2	Power On/Standby Button	6	Right Arrow Button
3	A - Button	7	B - Button
4	AC Power/Battery Charging Indicator		

- Enter “Test Access Mode”, and conduct the general function test (test mode T2) as per the Kendall SCD™ 700 system Operation and Service Manual.
- Verify battery status:
 - o Turn off the controller.
 - o Disconnect the controller from AC Power, and activate again.
 - o Confirm that battery charge level is at least 2/3 (i.e. 2 or 3 green battery status indicators).
 - o If battery charge level is less than 2/3, connect the controller to AC power, and leave connected to AC power until battery reaches at least 2/3 level.
- If operation of the SCD™ 700 controller is not correct as per the above tests, send the controller to the Covidien service center for repair (Attachment A).

Section 2 – Instructions for Customer Returned Units (continued)

KENDALL SCD™ 700 CONTROLLER (continued)

RE-PACKAGING PROCEDURE

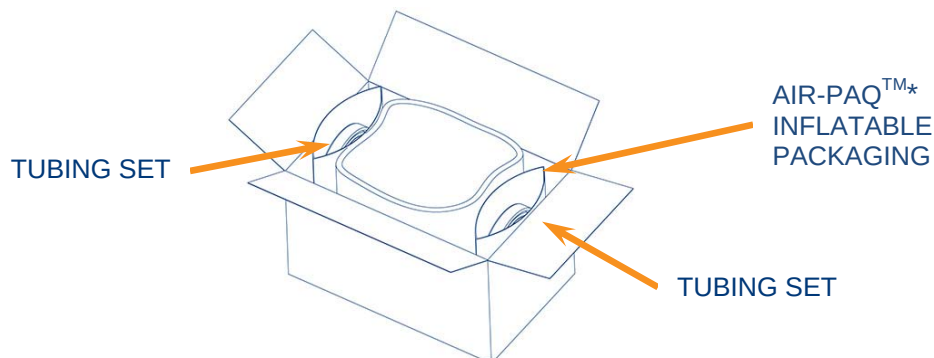
KIT MATERIALS

- o Verify that all materials are available, referencing the batch record.
- o List of materials required to re-package the kit is as follows:

Part Description	Quantity	Part #	Vendor	Contact Info
Kendall SCD™ 700 system corrugate case	1	1029053	Covidien	1-800-962-9888 www.covidien.com
Kendall SCD™ 700 system tubing sets (for replacements)	2	9528	Covidien	1-800-962-9888 www.covidien.com
Kendall SCD™ 700 system hospital DME shipping label	1	1077455	Covidien	1-800-962-9888 www.covidien.com
Return Label	1	N/A	N/A	N/A
Chip Board - AIR-PAQ™* Protector	1	1059428	Covidien	1-800-962-9888 www.covidien.com
Kendall SCD™ 700 system AIR-PAQ™* inflatable packaging	1	1031823	Covidien	1-800-962-9888 www.covidien.com
Polybag for Kendall SCD™ 700 controller	1	1033373	Covidien	1-800-962-9888 www.covidien.com
Polybag for tubing set	2	F123450	Covidien	1-800-962-9888 www.covidien.com
Twist Ties, Blue Plastic	1	F150023	Covidien	1-800-962-9888 www.covidien.com
Kendall SCD™ 700 controller QuickStart Guide	1	1066981	Covidien	1-800-962-9888 www.covidien.com
Kendall SCD™ 700 controller Printed IFU	1	1066980	Covidien	1-800-962-9888 www.covidien.com

PACKAGING INSTRUCTIONS

- o Using regulated air source set at 9-10 psi of pressure; inflate the AIR-PAQ™* inflatable packaging. If an air source is not available to inflate AIR-PAQ™* inflatable packaging, you should not ship the device. Hand delivery of the kit is recommended in this situation.
- o Tape the bottom surface of the shipping box.
- o Place the Chip Board in the box on the bottom surface. Place the Printed IFU in the shipping box on top of the Chip Board.
- o Place the AIR-PAQ™* inflatable packaging into the shipping box on top of the printed IFU. Place a tubing set on either side of the AIR-PAQ™* inflatable packaging as shown below.



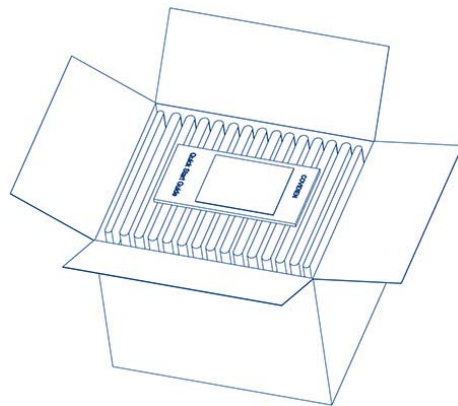
Section 2 – Instructions for Customer Returned Units (continued)

KENDALL SCD™ 700 CONTROLLER (continued)

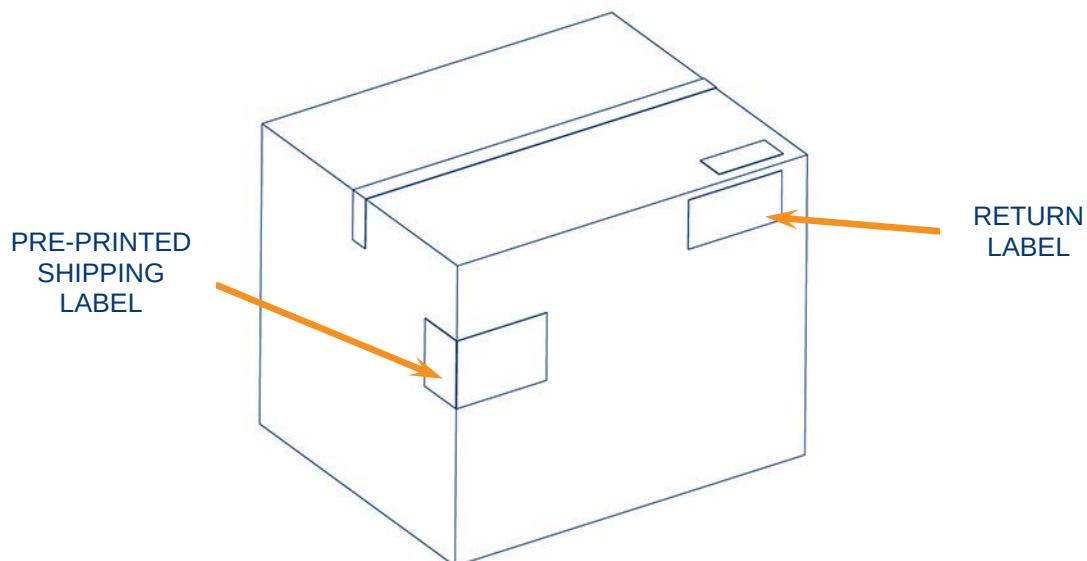
RE-PACKAGING PROCEDURE (continued)

PACKAGING INSTRUCTIONS (continued)

- o Verify that the DME supplier contact information label is on the Kendall SCD™ 700 controller. Place the controller into the polybag and use a twist tie to secure.
- o Place the Kendall SCD™ 700 controller in the AIR-PAQ™* inflatable packaging, and close the AIR-PAQ™* inflatable packaging.
- o Place the QuickStart Guide on top of the AIR-PAQ™* inflatable packaging as shown below:



- o Seal the top of the box and assemble the following labels on the outside of the shipping box as shown below:
 - ✓ Pre-printed shipping label on the front wrapping on the left side;
 - ✓ Return label to the right of the shipper label.



ATTACHMENT A: Instructions for Returning Damaged Controllers

To obtain service on your Covidien Kendall SCD™ 700 controller, you must contact the service department and request a Return Material Authorization Number (RMA).

Please contact the service department by:

1. Phone- 1-800-962-9888 opt 1/opt 1
2. Email: SWM.customerservice@covidien.com
3. CovidienConnect: <https://www.covidienconnect.com/>

Please have the following available when contacting the service department:

- Account Bill To
- Account Ship To
- Device Serial Number
- Reason for service/return
- Contact information for Estimate approval if applicable: (Name, Phone Number & Email address)

Repackage the Kendall SCD™ 700 controller carefully in its original box. List the RMA number on the shipping label or exterior of the box.

Equipment returned without RMA number will not be serviced!

Mail Device to:

Covidien
5290 Longbow Drive
Building 4 Service Dock
Boulder, Co 80301

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